Response to

Public Chapter 363
of the
Acts of the 2001 General Assembly

Methadone Treatment Facilities

Report prepared by

Tennessee Department of Health
in Consultation with the
Methadone Task Force,
Health Care Facilities Commission and
Board for Licensing Health Care Facilities

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(Note: Exhibits are not available for downloading.)

SCOPE OF REPORT

Due to the increased attention in the placement of methadone treatment facilities and the need for these facilities, the General Assembly charged the Commissioner of Health to conduct a study of methadone treatment facilities and report back to the House Health and Human Resources Committee and the Senate General Welfare, Health and Human Resources Committee on or before January 1, 2002.

Public Chapter 363 of the Acts of the 2001 General Assembly directs the Commissioner of Health to study issues relating to the need for and location of non-residential treatment facilities in the Certificate of Need process in consultation with the Health Facilities Commission and the Board for Licensing Health Care Facilities.

This report will contain reviews conducted of current federal and state regulations of methadone treatment facilities, state oversite of Tennessee facilities, literature on national concerns, regulations from other states, and reports from the Tennessee Board of Pharmacy.

To the extent possible, recommendations will be based on a thorough review of all data, nationally accepted facts, and practice standards of methadone facilities.

This report includes recommendations to current regulations utilized by state survey agencies and *Guidelines for Growth* used by the Health Facilities Commission in making decisions about need.

REPORT PROCESS

This study was conducted in monthly meetings with committee members being appointed by the Commissioner of Health. Monthly meetings were conducted on September 27, 2001, October 23, 2001, November 13, 2001, and December 18, 2001. A membership list is attached in the exhibits.

Task force members and Health Facilities Commission members were given an opportunity to review the draft report in order to make comments and suggestions prior to finalizing the report.

Some members expressed concerns about the proposed rule changes dealing with:

1) Observed testing and
2) Diversion Control Plan

These comments are attached in exhibits. **(Note: Exhibits are not available for downloading.)**

BACKGROUND

National Concerns

The November 1997 *National Institutes of Health Consensus Statement, Effective Medical Treatment of Opiate Addiction* estimated that only 115,000 of the total 600,000 estimated opiate-dependent persons in the U.S. were in methadone maintenance treatment (MMT) programs. The Consensus Statement reported that, "MMT is effective in reducing illicit opiate drug use, in reducing crime, in enhancing social productivity, and in reducing the spread of viral diseases such as AIDS and hepatitis." Although a totally drug-free state would be preferable, most opiate-dependent persons, according to research, cannot achieve and maintain this worthy target. MMT, as a substitute for a drug-free state, does reduce drug use, decrease criminal activity, provide an opportunity for employment and significantly improve quality of life for patients.

Opiate use has clear and well-defined health, employment and criminal consequences according to the Consensus Statement. The total financial costs of untreated opiate dependence to the individual, family and society was estimated at $20 billion by the NIH in its Consensus Statement. Numerous studies throughout the world have demonstrated that participation in MMT leads to significant reductions of illegal opiate use as well as other illicit drugs.

The mortality rate for opiate-dependent persons in methadone treatment programs is 30% of the mortality rate for those not participating in treatment. Persons who are not participating in MMT have higher incidence rates of bacterial infections, tuberculosis, hepatitis B and C, AIDS and other sexually transmitted diseases and alcohol abuse. Health care costs alone were estimated in the 1997 Consensus Statement to amount to $1.2 billion for opiate dependence.

Opiate use has an adverse impact upon employment and an individual's contribution to society. Since users spend an inordinate amount of time in finding and taking the drug, maintaining employment is often difficult. Many users look to public assistance to support themselves and their families. Studies have demonstrated, however, that MMT patients earn incomes that are double those of opiate users not in treatment.

Opiate use often leads users to criminal behavior. Stealing is the most common offense. The Consensus Statement reports that more than 95% of opiate users reported committing crimes in span of an 11-year period when they were using opiates. Numerous studies have demonstrated that "effective treatment of opiate dependence markedly reduces the rates of criminal activity."

Many persons associate dependency solely on heroin use. Too often, legally prescribed controlled substances, including opiates such as hydrocodone and morphine, are diverted for illegal use. In fact, the February 2001 edition of the *Psychiatric Times* reported that a national Substance Abuse and Mental Health Services Administration (SAMHSA) survey indicated that approximately 3.9 million Americans currently use prescription-type psychotherapeutic drugs for nonmedical reasons, almost twice as many as the 2.1 million who use heroin, cocaine and/or crack cocaine.

The NIH Consensus Statement addresses many of the misconceptions and stigmas associated with opiate dependence and methadone treatment programs. NIH urges that "vigorous and effective leadership is needed to inform the public that dependence is a **medical disorder** (emphasis added) that can be effectively treated with significant benefits for the patient and society."

Tennessee Problems

No public health data exist which accurately depicts the extent or severity of opiate addiction in Tennessee. Extrapolating the NIH estimates to Tennessee provides as reasonable an approach as any, resulting in estimates that 12,000 or more Tennesseans are opiate dependent. In December 2001, less than 3,000 persons were actively participating in non-residential treatment programs in the state which represents only a fraction of the state's estimated opiate users.

Generally, the closer one lives to a treatment program, the greater likelihood of participation. The current rate of participation is nearly twice as high for persons living in or close to one of the five counties (Shelby, Davidson, Knox, Hamilton and Madison) that house programs, 59.0/100,000 than the rate for those that live 60 miles or more from a program, 32.2/100,000.

The relatively few number of programs in the state that are available to opiate-dependent persons also contributes to low participation rates. Although the number of programs in other Southeastern states varies widely, Tennessee's six programs yields a rate of just 1.1 programs/one million population, less than one-half the 2.4/one million rate of the other states.

As is true around the country, substance abuse probably cannot be attributed solely to illegal substances in this state. Although Tennessee does not maintain a system for capturing data on the number of prescriptions filled, vendors in Tennessee cite the state as one of the top five in the country for purchase of Hydrocodone, Cocaine and Meperidine, all controlled substances that are easily diverted for illegal use.

Tennessee Regulatory Oversight

Tennessee Code Annotated requires that a vendor wanting to open a methadone treatment program must first receive a Certificate of Need from the Tennessee Health Facilities Commission and then be licensed by the Department of Health as a non-residential methadone treatment facility. Unfortunately, the *Guidelines for Growth* that have been developed do not provide concrete, objective criteria that can be used to adequately determine the appropriateness of awarding a Certificate of Need.

The regulatory oversight of Methadone Treatment Facilities began in 1988 by the Tennessee Department of Mental Health. In March, 1994 that oversight was transferred to the Department of Health, Health Care Facilities. Rules and regulation were amended by the Department in August, 1999 with encouragement and support of the General Assembly.

Currently there are 6 clinics operating in Tennessee in the following counties: Shelby, Davidson, Knox, Hamilton and Madison. Each clinic is surveyed annually and as necessary when complaints are filed.

For the past 2 years an average of 2 deficiencies have been sited per survey and consist of:

No Individual Treatment Record
Client history and treatment plans not reviewed every 90 days
No documentation of staff training for STD/HIV Training
Admission screening test not done – TB test, and pregnancy test for females
No annual justification for continued treatment
No evidence of annual physical
Urine drug screens not conducted on new clients
No physician's signature on medication order changes

There have been 3 complaints filed in the past two years.

FINDINGS OF FACT

During the review of the vast amount of materials and interviewing of individuals, the following facts were formulated and agreed upon by the panel:

- Businesses that establish programs require a general population of at least 100,000 persons from which to draw potential clients. This figure is believed to generate 67 clients on average. Private businesses normally will not establish a program unless a minimum caseload of 60 patients is available.

- The closer one lives to a treatment program, the greater likelihood of participation as based on current participation in Tennessee Methadone Treatment facilities -

  59.0/100,000 population participate in programs 60 miles or less
  32.2/100,000 population participate in programs over 60 miles

- The NIH Consensus Statement of November, 1997 estimated that only 115,000 of the total 600,000 estimated opiate-dependent persons in the U.S. were in methadone maintenance treatment programs.

- Applying the NIH 1997 Consensus statement estimates of approximately 20% of opiate-dependent persons to Tennessee Census data, the number of potential clients could be as high as 12,300 within the state indicating only a fraction of the opiate users in the state are currently participating in methadone treatment programs.

- The financial costs of untreated opiate dependence to the individual, family and society was estimated at $20 billion by the NIH in its Consensus Statement.

- Opiate use has clear and well-defined health consequences. The mortality rate for opiate-dependent persons in methadone treatment programs is 30% lower than for dependent persons not participating in treatment. Numerous studies have demonstrated that participation in methadone maintenance treatment programs (MMT) leads to significant reductions of illegal opiate use as well as other illicit drugs.

- Since no data exists otherwise, it was presumed that the prevalence of opium-dependence was similar throughout the state.

- From a public policy standpoint, placing persons in a nonresidential methadone treatment program is preferable than allowing persons to remain addicted to heroin or other opiates.

- All Tennesseans who are eligible for and choose to participate in nonresidential methadone treatment should have reasonable geographic access to a program.

- Access should allow participants to develop a life that could include full employment and meaningful contributions to society.

❖ The number of reported methadone treatment facilities per SAMHSA in neighboring states varies widely:

STATE	**#**	**Rate/one million population**
Alabama	17	3.8
Arkansas	3	1.1
Georgia	24	2.9
Kentucky	15	3.7
Mississippi	2	.7
Missouri	12	2.1
North Carolina	18	2.7
Tennessee	6	1.1
Virginia	14	2.3

SUMMARY

In response to Public Chapter 363 of the Acts of 2001, the Commissioner of Health assembled a Methadone Task Force comprised of persons interested and involved in the subject of Methadone Maintenance Treatment (MMT). This task force held several meetings between September 1, 2001 and December 21, 2001 and examined a vast array of information related to Methadone programs, both in Tennessee and throughout the country. Many items that were considered by the group are attached to this report as exhibits.

New federal regulations for MMT were implemented on March 19, 2001. The task force examined the differences in existing Tennessee regulations and the new federal regulations in an effort to determine what changes were needed to the state's regulations for Non Residential Narcotic Treatment Facilities in order to assure compliance and compatibility with the new federal guidelines. In addition to reviewing the new federal regulations, the group reviewed other state regulations for comparison as well. Suggestions and comments were solicited from the methadone industry, methadone treatment specialists and the Department's Bureau of Alcohol and Drug Abuse Services for input on recommendations that would best serve to protect the public health, safety and welfare of the citizens of Tennessee.

Information from the state's Central Registry of Methadone patients in treatment was compiled, analyzed and studied by members of the group. Both the number and participation rate of active patients in treatment per county of residence was determined. Distance was a strong predictor of participation rates. Assuring that all Tennesseans who wish to participate in MMT have reasonable access to a program was used as justification for planning purposes of the proposal to designate 23 Methadone Service Areas (MSA) within the state. An MSA is a county or constellation of contiguous counties in the state that comprise a sufficient general population making it likely that a minimum number of opiate dependent persons reside in the MSA who wish treatment and could support a program. This minimum population foundation was balanced with the need to establish geographic boundaries such that patients living within the MSA would reside within less than an hour drive one-way to a treatment program if the program were established in the heart of the MSA. Refer to exhibit #6 for proposed MSAs.

The Tennessee Board of Pharmacy provided to the panel the DEA's Retail Drug Distribution by Zip Code report for Tennessee. This detailed report showed what prescription drugs were being shipped to various areas of the state. Also provided to the group was the information that revealed Tennessee's ranking in the purchasing of legally prescribed drugs. This report revealed Tennessee in the top five nationally for the purchase of Cocaine, Hydrocodone, and Meperidine (Demerol), each of which can be readily converted to illicit use that contributes to the high rate of opiate dependency in the state.

Although the current Guidelines for Growth were adopted by the Department and the Health Planning Commission in 2001, they still remain vague and lack the specificity as needed to support the philosophy of directing the delivery of health care services for methadone treatment. The group reviewed the current criteria and standards used for assisting the Health Facilities Commission in decisions concerning certificate of need application and felt improvements should be made.

Incorporating the concept of the Methadone Service Areas (MSAs), adding distance in travel time to existing programs and the impact on employment opportunities would strengthen the quality of the information submitted to the Commission when agencies request a Certificate of Need (CON). More comprehensive information would contribute to better decisions relating to need, economic feasibility, and orderly contribution to development of adequate and effective methadone treatment programs and assist the Department and the Health Facilities Commission in determining the appropriateness of issuing a CON.

RECOMMENDATIONS

As a result of these efforts the Task Force is issuing recommendations within this report relating both to proposed rules changes and changes to the Guidelines for Growth. These recommendations follow in the papers titled "Proposed Rule Amendments to Chapter 1200-8-21 Non-Residential Narcotic Treatment Facilities" and "Guidelines for Growth Proposed Amendments".

Recommendations of the Methadone Task Force
December 2001

Proposed Rule Amendments to Chapter 1200-8-21 Non- Residential Narcotic Treatment Facilities

1200-8-21-.01 Definitions.
Recommendation: Add the following definitions:

1. Counseling Session. Therapeutic discussion between client(s) and a facility counselor for a period of no less than thirty (30) minutes designed to address client addiction issues or coping strategies and treatment plans.

Rationale: *Establishes a minimum standard for a counseling session*

2. Observed Testing. Testing conducted and witnessed by a facility staff person to ensure against falsification or tampering of results of a drug screen.

Rationale: *Clarification of testing procedure.*

3. Random Testing. Drug screens conducted by the facility that lack a definite pattern of who and when clients are selected for testing; indiscriminate testing.

Rationale: *Clarification of current regulatory language.*

4. Relapse. The failure of a client to maintain abstinence from illicit drug use verified through drug screen.

Rationale: *To clarify proposed amended language.*

1200-8-21-.02 Licensing Procedures.
Recommendation: Propose amending the following:
1200-8-21-0.2(2)(a). Delete … "rules of the FDA…" and replace with "…rules of SAMSHA (Substance Abuse and Mental Health Services Administration)…"

Rationale: *This change allows Tennessee's regulations to be aligned with those guidelines from the Federal agency, as they have been in the past.*

1200-8-21-.04 Administration.

Recommendation: Propose amending the following:

1. 1200-8-21-.04(4)(f) Counselors. Delete current language and replace with the following: There must be sufficient group and individual counseling available to meet the needs of the client population. At a minimum, the following counseling schedule shall be followed:
    (i) During 1st 90 days of treatment, counseling session(s) shall take place at least one time a week;
    (ii) During 2nd 90 days of treatment, counseling session(s) shall take place at least three (3) times per month;
    (iii) During the 3rd 90 days of treatment, counseling session(s) shall take place at least two (2) times per month;
    (iv) For subsequent 90 day periods of treatment, counseling session(s) shall take place as needed or indicated in the client's treatment plan, but no less frequent than monthly as long as the client is compliant;
    (v) If the client experiences a relapse, his/her individualized treatment plan must document evidence of intensified services provided. Such evidence may include, but is not limited to, increase in individual or group counseling session(s) and/or a reduction in the client's take home privileges.

Rationale: *A specific counselor to client ratio has proven to be a difficult item to measure and does not dictate the quality of counseling provided. This change is directed at establishing the minimum standard and reflects the Federal change to accreditation rather than regulation. This should allow more flexibility for the clinics to establish quality counseling programs that achieve the desired outcomes necessitated for accreditation.*

2. 1200-8-21-.04(21). Hours of Operation. Propose amending the following:

Delete the third sentence that states, "In order to accommodate clients who are not receiving take-home medication, facilities must be open for dispensing seven days per week."

Replace with: Any patient in comprehensive maintenance treatment may receive a single take-home dose for each day that the clinic is closed for business, including Sundays and State and Federal holidays, not to exceed two (2) consecutive days.

Rationale: *Would potentially result in improved client compliance and an orderly provision of services.*

3.1200-8-21-.04, (f) 24.

Propose adding the following language:

A Diversion Control Plan shall be in place at each clinic. The Diversion Control Plan must contain, at a minimum, the following:

(i) The Diversion Control Plan shall apply to all clients receiving take home medication.

(ii) It will include a random call back program with mandatory compliance. This call back must be in addition to the regular schedule of clinic visits.

(iii) Each client receiving take-home medications must be called back at a minimum of once per 3 months.

(iv) Upon call back a client must report to the clinic within 24 hours of notification, with all take home medications. The quantity and integrity of packaging shall be verified. One dose must be replaced and sent for analysis to verify strength and contents.

(v) The facility shall maintain individual callback results in the client record.

(vi) The facility must maintain a current log of all callbacks with the results of compliance.

Rationale: *Methadone diversion is always a concern both from the clinic standpoint and in the community in which it is located. This rule establishes minimum standards and requires each facility to develop callback plans for diversion control. .*

1200-8-21-.05 Admissions, Discharges and Transfers.

Recommendation: Propose to amend the following:

1. 1200-8-21-.05(4)(a) Amend third sentence to read, "Within 72 hours of admission **or discharge**, the facility shall initiate a clearance inquiry by submitting to the approved central registry the name, date of birth, anticipated date of admission **or discharge**…"

Rationale: *In order for the Central Registry to remain current in information, the SNA must be notified of discharges as well as admissions.*

2. Add the following language: The facility shall ensure that clients are instructed in the proper storage and security of take-home medications after they leave the facility.

Rationale: *To provide for the safe storage and handling of take-home medications to protect general welfare of the public.*

1200-8-21-.06 Basic Services.

1. 1200-8-21-.06(5)(h).

Recommendation: Add the following language:

Each clients' individualized treatment plan must include the counseling needs, including both group and individual counseling sessions as indicated by evaluation of the client's length of time in the program, drug screening results, progress notes, and social environment. The treatment plan must be reviewed at least every six (6) months.

2. 1200-8-21-.06(8)(a). Drug Screens. Delete the word Urine.

Rationale*: This will allow the use of alternative drug screening at the discretion of the clinic. There are alternative tests available such as saliva and hair that are less invasive for the client, less opportunity for dilution/contamination. Currently they are prohibited from use in Tennessee because this regulation only recognizes urine drug screening*

3. 1200-8-21-.06(9)(c)Take Home Doses. Amend by adding … "methadone **and LAAM**"

Rationale: *This allows Tennessee regulations to be in conformity with the Federal Regulations.*

4. **1200-8-21-.06 (9) (c)**

Recommendation: Propose amending the following:

… "rules of the FDA…" and replace with "…rules of SAMSHA (Substance Abuse and Mental Health Services Administration)…"

Rationale: *This change allows Tennessee's regulations to be aligned with those guidelines from the Federal agency, as they have been in the past.*

Guidelines for Growth-proposed amendments

1. Need determinations for non-residential methadone treatment facilities shall strongly consider the Methadone Service Area. [Methadone Service Areas (MSAs) are designated for planning purposes to assist the state agencies in determining the appropriateness of issuing a Certificate of Need. These MSAs were developed in response to assumptions developed by a committee established in response to Public Health Chapter 363 of the Acts of 2001.]

   Designation of MSAs was patterned, in concept, after the use of Rational Service Areas by the Department of Health in helping identify underserved health resource shortage areas in Tennessee. An MSA is a county or constellation of contiguous counties in the state that comprise a sufficient general population making it likely that a minimum number of opiate dependent persons reside in the MSA who wish treatment and could support a program. This population foundation was balanced with the need to establish geographic boundaries such that patients living within the MSA would reside within less than an hour drive one-way to a treatment program if it were established in the heart of the MSA. Assumptions that guided determination of MSAs:

   - Generally, the closer one lives to a treatment program, the greater likelihood of participation. The rate of participation is nearly twice as high for persons living in or close to one of the five counties that house programs, 59.0/100,000 than the rate for those that live 60 miles or more from a program, 32.2/100,000
   - Businesses that establish programs require a general population of no less than100,000 persons from which to draw potential clients. This figure is believed to generate 67 clients on average. Private businesses normally will not establish a program unless a minimum caseload of 60 patients is available.
   - In order to assure a sufficient population base in each MSA to support a treatment program, boundaries of MSAs were drawn to include a general population of 200,000. (Identification of MSAs with less population, e.g. 150,000, led to some areas with barely sufficient population to support a program; more than 200,000 would perpetuate distance barriers to existing programs.)

2. Decisions should be predicated upon improving access to programs that will increase patient compliance and reduce dropout rates and recidivism.

3. Access determinations should include the distance in miles and approximate travel time to the nearest existing programs. Consideration should be given to the quality of life improvements and employment opportunities available if programs were geographically accessible.
4. Strong consideration should be given to an applicant in a multi-county MSA without an existing program if Need, Economic Feasibility and Contribution to Orderly Development are met.
5. Simultaneous review CON applications for programs in the same MSA or a CON application in an MSA where at least one program already exists should demonstrate:
    -Current and potential caseloads
    -Estimated current unmet needs
    -Prospects for long-term viability if multiple programs are approved
    -Experience of the applicant in other locations (in- or out-of-state)
6. The applicant shall provide documentation on any agency in- or out-of-state with which the applicant has legal interest in or is involved in a management role.
7. The Department of Health's application review (TCA 68-11-107) will include recommendations from the State Methadone Authority. Both the Department and the Commission shall consider the State Methadone Authority's quarterly Tracking Report (description of patient census by county of residence).

Exhibits

(Note: Exhibits are not available for downloading.)

Exhibit 1	Committee Members
Exhibit 2	Public Chapter 363
Exhibit 3	Non Residential Narcotic Treatment Facility Outcome/Performance Data 1997, 1998, 1999 & 2000
Exhibit 4	Methadone Registry
Exhibit 5	County 2000 Population
Exhibit 6	Possible Methadone Service Areas for NR Methadone Clinic Locations
Exhibit 7	Map
Exhibit 8	Non-Residential Methadone Treatment Facilities (NRMTF)
Exhibit 9	Federal State
Exhibit 10	Chapter 1200-8-21 Rules for Alcohol and Other Drugs of Abuse Non-Residential Narcotic Treatment Facilities
Exhibit 11	Federal Register
Exhibit 12	Retail Drug Distribution
Exhibit 13	1999 Highlights
Exhibit 14	Certificate of Need and Rule Revision Recommendations
Exhibit 15	Volunteer Treatment Center, Inc.

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